



UNITED STATES DEPARTMENT OF COMMERCE  
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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/317,407 10/03/94 CARLING

C 1103326018

EXAMINER  
HENLEY III, R

12M2/0830

ART UNIT PAPER NUMBER

WHITE & CASE  
PATENT DEPARTMENT  
1155 AVENUE OF THE AMERICAS  
NEW YORK NY 10036

1205

17

DATE MAILED:

08/30/95

08/30/95

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on 5/25/95 6/12/95 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s),        days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.             | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152.       |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input checked="" type="checkbox"/> <u>Interview Summary</u>                   |

Part II SUMMARY OF ACTION

1. ☒ Claims 1, 2, 7 AND 14-23 are pending in the application.  
Of the above, claims        are withdrawn from consideration.
2. ☐ Claims        have been cancelled.
3. ☐ Claims        are allowed.
4. ☒ Claims 1, 2, 7 AND 14-23 are rejected.
5. ☐ Claims        are objected to.
6. ☐ Claims        are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on       . Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on       , has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed       , has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no.       ; filed on       .
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

**CLAIMS 1, 2, 7 AND 14-23 ARE PRESENTED FOR EXAMINATION**

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Applicants' amendment filed May 25, 1995 and the declaration of Dr. Jan Trofast filed June 12, 1995 have been received and entered into the application. Accordingly, the title, specification and claims 1, 2 and 7 have been amended; claims 3, 5, 6 and 8-13 have been cancelled; and claims 14-23 have been added.

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Claims 1, 2, 7 and 14-23 are rejected under 35 U.S.C. § 103 as being unpatentable over Brattsand et al. and Murakami et al., in view of applicants' acknowledgements at page 3 of the specification, for the reasons of record as maintained in the last Office action dated December 23, 1994 at page 2 as applied to claims 1-3 and 5-13.

Applicants' arguments and the declaration of Dr. Trofast have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

While it is accepted that the data contained in Dr. Trofast's declaration demonstrate unexpected activity for formoterol and budesonide combinations and that such is predictive of results that would occur in the treatment of asthma and other inflammatory respiratory disorders, it is noted that none of the present claims are as limited as the data with respect to the amount/proportions of ingredients employed. Applicants are reminded that a showing of non-obviousness

must be commensurate in scope with the claims which the evidence is offered to support. Perrin v. Kalk, 1 U.S.P.Q.2d 1881 (BPAI 1986).

The broadest allowable claim, whether directed to a method or composition, supported by the data would be one which recites that the amount of the combination of formoterol and budesonide is an effective amount and that the ratio of formoterol to budesonide ranges from 1:1 to 1:20.

While the Examiner recognizes that the probative value of a narrow range of data can, in some instances, be extended to prove the unobviousness of a broader claimed range, such is only the case when one could ascertain a trend in the exemplified data which would allow him/her to reasonably extend the probative values thereof. In re Clemens et al., 206 U.S.P.Q. 289 (CCPA 1980). Due to the unpredictable nature of synergism, it is not seen that a trend could be ascertained to permit the Examiner to extend his finding to support the present claims which either are unrestricted to the ingredient ratios or those which recite a broader range of ratios, i.e., claims 19, 22 and 23.

Accordingly, for the above reasons, the claims are deemed to be properly rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

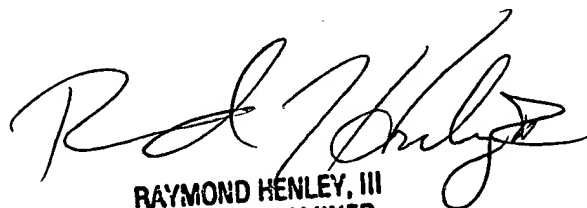
A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS

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Art Unit: 1205

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ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is (703) 308-4652.

  
RAYMOND HENLEY, III  
PRIMARY EXAMINER  
GROUP 1200

Henley; rjh  
August 28, 1995